UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 14, 2021

Landos Biopharma, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39971**	**81-5085535**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1800 Kraft Drive, Suite 216 **Blacksburg, Virginia** **(Address of Principal Executive Offices)**	**24060** **(Zip Code)**

(540) 218-2232
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $0.01 per share	**LABP**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 1.01 Entry into a Material Definitive Agreement.

On May 14, 2021, Landos Biopharma, Inc., or the Company, entered into an exclusive collaboration and license agreement, or the LianBio Agreement, with LianBio Respiratory Limited, or LianBio, pursuant to which the Company granted LianBio an exclusive license to develop, manufacture and commercialize the Company's product candidates omilancor and NX-13, each a Licensed Product, in Greater China (mainland China, Hong Kong, Taiwan and Macau), South Korea, Singapore, Thailand, Vietnam, Myanmar, Cambodia, Indonesia, and the Philippines, or the Territory.

Under the terms of the LianBio Agreement, the Company will receive an upfront cash payment of $18.0 million in connection with the execution of the LianBio Agreement and is eligible to receive development milestone payments of up to $95.0 million and sales milestone payments of up to $105.0 million. The Company is also eligible to receive tiered low-double-digit royalties based on net sales of Licensed Products in the Territory, subject to reduction in specified circumstances.

The Company and LianBio will form a joint steering committee to oversee and manage the collaboration. LianBio must use commercially reasonable efforts to develop and seek regulatory approval for the Licensed Products in the Territory, including funding all such expenses, while the Company will continue to have primary responsibility for clinical development and regulatory activities for the Licensed Products in all other geographies. If the Company conducts a global Phase 3 trial for omilancor or NX-13, LianBio will participate in such trial, including by opening clinical trial sites in the Territory, using commercially reasonable efforts to enroll a meaningful number of patients in the Territory and being responsible for any costs and expenses incurred by or on behalf of LianBio for such participation.

Unless earlier terminated, the LianBio Agreement will automatically terminate until the expiration of the royalty term applicable to such Licensed Product and such region in the Territory. The LianBio Agreement may be terminated prior to its expiration by either party upon the other party's material breach of the LianBio Agreement that is not cured within the specified cure period based on the nature of such breach, by either party in the event of either party's bankruptcy, insolvency or certain similar occurrences, by the Company if LianBio brings any action or proceeding challenging the validity or enforceability of any of the licensed patents, and by LianBio, for convenience. Upon termination of the LianBio Agreement, LianBio grants to the Company a worldwide, irrevocable, perpetual, transferable, exclusive license under LianBio's patent rights and product inventions to develop, manufacture and commercialize compounds and Licensed Products covered by the LianBio Agreement in the Territory.

The foregoing is a summary description of certain terms of the LianBio Agreement, is not complete and is qualified in its entirety by reference to the text of the LianBio Agreement, which the Company expects to file as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2021.

Item 2.02 Results of Operations and Financial Condition.

On May 17, 2021, the Company issued a press release announcing its financial results for the quarter ended March 31, 2021. This press release has been furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or, the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On May 17, 2021, the Company issued a press release to announce the entry into an exclusive collaboration and license agreement with LianBio. This press release has been furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01, and Exhibit 99.2 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or, the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant's filings under the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated May 17, 2021
99.2	Press Release, dated May 17, 2021
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on May 17, 2021, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Landos Biopharma, Inc.

Dated: May 17, 2021

By: /s/ Josep Bassaganya-Riera
Josep Bassaganya-Riera
Chief Executive Officer

Exhibit 99.1

Landos Biopharma Reports First Quarter 2021 Financial Results and Provides Business Updates

Completed initial public offering of common stock, raising approximately $100 million in gross proceeds

Following positive Phase 2 results of omilancor in ulcerative colitis, including statistically significant immunological and biomarker results, end-of-Phase 2 Meeting with FDA planned for Q2 2021

Announced a potentially $218 million exclusive development and commercialization agreement with LianBio to conduct two clinical trials for omilancor and NX-13 in Greater China and select Asian markets

Company expects to file at least three INDs in 2021

BLACKSBURG, Va., May 17, 2021 — Landos Biopharma, Inc (NASDAQ: LABP), a clinical-stage biopharmaceutical company focused on the discovery and development of therapeutics for patients with autoimmune diseases, today announced financial results for the first quarter ended March 31, 2021 and provided business updates.

“We delivered on numerous significant milestones during the first quarter of 2021, including our successful initial public offering and Nasdaq listing, initiation of two clinical trials for omilancor and NX-13, a partnership with LianBio potentially worth in excess of $218 million in upfront, development and commercial milestone payments, as well as reported positive clinical study readouts,” said Josep Bassaganya-Riera, Ph.D., Chairman, President, and CEO of Landos. “In February, we reported proof-of-concept data from the Phase 2 trial in ulcerative colitis, in which omilancor induced clinical and histological remission in a subset of patients that compared favorably to the rates seen in standard of care treatments. These supportive data of omilancor as a Phase 3-ready product candidate will be important for the upcoming end-of-Phase 2 meeting with the FDA in Q2 2021.”

Josep Bassaganya-Riera added, “On the heels of positive results from a Phase 1a study in NX-13 where all endpoints were met, we subsequently initiated a Phase 1b trial of NX-13 in patients with ulcerative colitis and anticipate topline results in Q1 2022. We have also initiated a Phase 2 study of omilancor in moderate-to-severe Crohn’s disease patients. We believe the success of our two lead candidates to date is linked to Landos’ differentiated approach to discover novel pathways through our proprietary LANCE advanced A.I. platform. We recently made several enhancements to LANCE, which will help us continue to identify the next generation of therapeutic targets and biomarkers. Following our IPO in which we raised approximately $100 million, Landos maintains a strong cash position and operating runway, expected through the end of 2023.”

Recent Highlights and Upcoming Milestones:

Omilancor (BT-11)

Omilancor is a novel, oral, gut-restricted LANCL2 agonist in development for the treatment of ulcerative colitis (UC), Crohn’s disease (CD) and Eosinophilic Esophagitis (EoE). A topical form of omilancor is in development for psoriasis and atopic dermatitis.

- In May 2021, Landos reported additional positive data from its Phase 2 trial in UC. The results demonstrated that omilancor induced increased levels of regulatory CD4+ T cells and myeloid cells and increased IL-10 expression in remitters ($p = 0.036$) as well as decreased TNF-a expressing myeloid cells ($p = 0.037$). These results are consistent with normalization of fecal calprotectin, occurring in 43.8% of patients (1000 mg of omilancor) and 40.6% of patients (500 mg of omilancor) compared to 21.4% of patients receiving placebo ($p = 0.048$) after 2 weeks of treatment.

- In May 2021, Landos initiated a Phase 2 trial of omilancor designed to evaluate proof-of-concept efficacy and safety of omilancor for the treatment of moderate-to-severe CD. Results from the Phase 2 study are expected in Q2 2022.
- In May 2021, Landos' presented a late-breaking abstract of omilancor in psoriasis at the 2021 American Association of Immunologists (AAI) Annual Meeting. The data showed that omilancor, when delivered topically, could significantly suppress inflammation and reduce disease severity in preclinical mouse models of psoriasis by activating key immunometabolic mechanisms.
- In April 2021, the U.S. Food and Drug Administration (FDA) cleared the Company's IND application of omilancor for the treatment of Eosinophilic Esophagitis (EoE). This product candidate's new oral formulation is designed to enable exposure to omilancor in the upper gastrointestinal tract while retaining local action without systemic exposure. Landos expects to initiate a Phase 1b trial of omilancor for this indication in 2022.
- In February 2021, the Company reported positive translational data from its Phase 2 trial for patients with mild-to-moderate UC. Overall, orally-administered omilancor was gut-restricted and well tolerated, with no treatment-related significant adverse events and it induced statistically significant changes in biomarkers. Based on this data, Landos plans to consult with the FDA on an end-of-Phase 2 meeting in Q2 2021, which has the potential to shape our future path to a Phase 3 pivotal trial for omilancor in UC.

NX-13

A novel, oral, gut-restricted NLRX1 targeting compound in development for the treatment of UC and CD.

- In April 2021, the Company initiated a Phase 1b study of NX-13 to investigate the safety and pharmacokinetics of multiple dose levels of this product candidate in UC patients with active disease. Topline data from this trial is expected to readout in Q1 2022.
- In March 2021, Landos reported positive results from a Phase 1a study of NX-13 that met all endpoints in healthy volunteers, demonstrating that the candidate was well-tolerated and gut-restricted pharmacokinetics and dose-dependent changes in fecal calprotectin were also observed. The maximum tolerated dose was identified to be 10-fold greater than the anticipated therapeutic dose.

PX-69

An oral PLXDC2 agonist for the treatment of rheumatoid arthritis and diabetic nephropathy.

- In May 2021, Landos presented a late-breaking abstract of PX-69 in rheumatoid arthritis at the 2021 AAI Annual Meeting. The preclinical data demonstrated that activating the PLXDC2 pathway led to a decrease of inflammation and enhanced preservation of joint structure in animal models.

- Landos expects to commence IND-enabling studies of PX-69 in the 2H 2021.

Corporate Highlights:

- In May 2021, Landos entered into a collaboration and license agreement with LianBio to develop and commercialize omilancor and NX-13 in Greater China and select Asian markets. Landos will receive an upfront cash payment of $18 million from LianBio and is eligible to receive development and commercial milestone payments of up to $200 million as well as low- to mid-double-digit royalties on omilancor and NX-13 net sales in the licensed territories. LianBio will participate in future global Phase 3 trials in Greater China and select Asian markets by enrolling a meaningful number of patients in these studies.
- In February 2021, Landos completed an IPO in which the company issued and sold 6,250,000 shares of its common stock for net proceeds of $90.5 million. Landos expects its cash, cash equivalents and marketable securities, including the IPO net proceeds, will be sufficient to support Landos' operating costs through the end of 2023.

First Quarter 2021 Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** As of March 31, 2021, the Company had cash, cash equivalents and marketable securities of $106.4 million, which it believes will be sufficient to fund its planned operations through the end of 2023. This amount does not include the $18 million upfront payment associated with the LianBio development and commercialization agreement.
- **Research and Development ("R&D") Expenses:** Research and development expenses were $7.3 million for the three months ended March 31, 2021 compared to $4.7 million for the three months ended March 31, 2020. The increase of $2.6 million was primarily attributable to increased costs associated with ongoing clinical trial activities for omilancor and NX-13.
- **General and Administrative ("G&A") Expenses:** General and administrative expenses were $2.6 million for the three months ended March 31, 2021 compared to $1.1 million for the three months ended March 31, 2020. The increase of $1.5 million was primarily attributable to increases in patent costs and cost associated with becoming a publicly traded company.
- **Net Loss:** Our net loss was $9.8 million and $5.8 million for the three months ended March 31, 2021 and 2020, respectively.

About Omilancor (BT-11)

Discovered using Landos proprietary LANCE A.I. platform, omilancor is a novel, gut-restricted small molecule investigational drug that targets the Lanthionine Synthetase C-Like 2 (LANCL2) pathway impacting the gastrointestinal tract. LANCL2 plays an important role in the immunoregulatory process. By activating the LANCL2 pathway and modulating the interactions between immunological and metabolic signals in immune cells, omilancor is designed to create a favorable regulatory microenvironment in the gut, decreasing the production of key inflammatory mediators and increasing

anti-inflammatory markers in regulatory T cells (Treg) within the site of inflammation. The Company reported initial Phase 2 results of omilancor evaluating patients with ulcerative colitis in 2021 and expects to initiate a Phase 3 trial in the second half of 2021. Additionally, Landos initiated a Phase 2 trial of omilancor in patients with Crohn's disease in the first half of 2021

About NX-13

Discovered using Landos' proprietary LANCE A.I. platform, NX-13 is a first-in-class, gut-restricted, small molecule therapeutic candidate for the treatment of ulcerative colitis (UC) and Crohn's disease (CD). NX-13 targets NLRX1, a mitochondria-associated receptor with the ability to modulate immune responses. By activating the NLRX1 pathway, NX-13 increases autophagy and oxidative phosphorylation in immune cells, while decreasing differentiation of effector CD4+ T cells, reactive oxygen species, inflammasome formation and production of inflammatory cytokines. The Company reported positive results from the Phase 1a study of NX-13 in healthy volunteers in Q1 2021 and initiated a Phase 1b study of NX-13 in patients with ulcerative colitis in Q2 2021.

About Landos Biopharma

Landos Biopharma is a clinical-stage biopharmaceutical company utilizing its LANCE A.I. platform to discover and develop novel oral therapeutics for patients with autoimmune diseases. LANCE has discovered new mechanisms of action, including the LANCL2, NLRX1 and PLXDC2 immunometabolic pathways. Landos Biopharma has 17 active development programs targeting these novel pathways at the interface of immunity and metabolism. Lead asset omilancor is a novel gut-restricted small molecule drug candidate for the treatment of ulcerative colitis, Crohn's disease and Eosinophilic Esophagitis that targets the LANCL2 pathway. NX-13 is a novel, gut-restricted small molecule drug candidate for the treatment of inflammatory bowel disease, that targets the NLRX1 pathway. Additional candidates are in development for the treatment of lupus nephritis, rheumatoid arthritis, multiple sclerosis, and diabetes. For more information, please visit www.landosbiopharma.com.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Landos Biopharma, Inc. (the "Company"), including statements about the Company's strategy, clinical development and regulatory plans for its product candidates, the Company's anticipated milestones and future expectations and plans and prospects for the Company and other statements containing the words "anticipate", "plan", "expect", "may", "will", "could", the negatives thereof, variations thereon and similar expressions, or by discussions of strategy constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company's product candidates and other similar risks. Risks regarding our business are described in detail in our Securities and Exchange Commission ("SEC") filings, including in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, which are available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that we make from time to time with the SEC. Such risks may be amplified by the impacts of the COVID-19 pandemic. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to

update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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Landos Biopharma, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 8,572	$ 2,416
Marketable securities, available for sale	97,786	25,718
Incentive and tax receivables	1	154
Prepaid expenses and other current assets	3,386	202
Deferred offering costs	—	1,398
Total current assets	109,745	29,888
Property, plant and equipment-net	465	444
Total assets	$ 110,210	$ 30,332
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 8,200	$ 8,606
Accrued liabilities	364	1,939
Other current liabilities	255	489
Total current liabilities	8,819	11,034
Other liabilities	212	276
Total liabilities	9,031	11,310
Commitments and Contingencies	—	—
Convertible preferred stock, $0.01 par value; no shares authorized, issued or outstanding as of March 31, 2021; 11,260,608 shares authorized, issued and outstanding as of December 31, 2020: aggregate liquidation preference of $70,254 as of December 31, 2020	—	73,037
Stockholders' equity (deficit):		
Preferred stock, $0.01 par value; 10,000,000 shares authorized, no shares issued or outstanding as of March 31, 2021 Common stock, $0.01 par value; 200,000,000 shares authorized, 39,866,669 shares issued and outstanding as of March 31, 2021; 12,767,909 shares issued and outstanding as of December 31, 2020	399	71
Additional paid-in-capital	166,429	1,633
Accumulated other comprehensive (loss) gain	(102)	10
Accumulated deficit	(65,547)	(55,729)
Total stockholders' equity (deficit)	101,179	(54,015)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 110,210	$ 30,332

Landos Biopharma, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 7,254	$ 4,690
General and administrative	2,646	1,080
Total operating expenses	9,900	5,770
Loss from operations	(9,900)	(5,770)
Other income (expenses):		
Interest expense	—	(1)
Gain/(loss) from foreign exchange	18	(222)
Other income, net	64	197
Other income (expense), net	82	(26)
Net loss	(9,818)	(5,796)
Net loss per share, basic and diluted	(0.38)	(0.49)
Weighted-average shares used to compute net loss per share, basic and diluted	26,070,455	11,874,723
Net loss	(9,818)	(5,796)
Unrealized gain/(loss) on available-for-sale securities	(112)	(686)
Comprehensive loss	(9,930)	(6,482)

Exhibit 99.2

Landos Biopharma and LianBio Announce Exclusive Collaboration and License Agreement to Develop and Commercialize Omilancor and NX-13 in Greater China and Select Asian Markets

Blacksburg, Va., & Shanghai, China and Princeton, N.J., May 17, 2021 - Landos Biopharma, Inc (NASDAQ: LABP), a clinical-stage biopharmaceutical company focused on the discovery and development of therapeutics for patients with autoimmune diseases, and LianBio, a biotechnology company dedicated to bringing paradigm-shifting medicines to patients in China and other major Asian markets, today announced an exclusive collaboration and license agreement for the development and commercialization of omilancor and NX-13 in Greater China (mainland China, Hong Kong, Taiwan and Macau) and select Asian markets. Omilancor is a novel, oral, gut-restricted LANCL2 agonist in development for the treatment of ulcerative colitis (UC), Crohn's disease (CD) and Eosinophilic Esophagitis (EoE). NX-13 is a novel, oral, gut-restricted NLRX1 targeting compound in development for the treatment of UC and CD.

"We are excited to collaborate with LianBio to strategically integrate their clinical and operational expertise in major Asian markets as we expand into global development programs with our innovative autoimmune disease pipeline," said Josep Bassaganya-Riera, Chairman, President and Chief Executive Officer of Landos. "Our lead product candidates, omilancor and NX-13, are designed to have critical advantages over current therapies, including the capacity to target key and novel pathways specifically linked to immune function. The opportunity to capitalize upon LianBio's resources in Asian markets will enable us to leverage the full value of our assets globally and bring our potentially more effective and better tolerated first-in-class oral therapeutics to patients with UC and CD in Greater China and select Asian markets."

Under the terms of the collaboration, LianBio will receive exclusive rights to develop and commercialize omilancor and NX-13 in Greater China, South Korea, Singapore, Thailand, Vietnam, Myanmar, Cambodia, Indonesia, and the Philippines. Landos will receive an upfront cash payment of $18 million and is eligible to receive development and commercial milestone payments of up to $200 million. Landos is also eligible to receive tiered low double-digit royalties based on net sales of omilancor and NX-13 in the licensed territories. LianBio will participate in future global Phase 3 trials of omilancor and NX-13 by enrolling a meaningful number of patients in these studies. LianBio will fund development and commercialization expenses in the collaboration territory, and Landos will continue to fund all development and commercialization expenses in all other geographies.

"We believe Landos' differentiated approach to the discovery and development of first-in-class oral therapeutics to target novel immunometabolic pathways has the potential to transform the treatment paradigm for CD, UC and other autoimmune diseases," said Konstantin Poukalov, Managing Director, Perceptive Advisors and Executive Chairman, LianBio. "With inflammatory

bowel disease incidence projected to significantly increase throughout Asia over the coming decade, we look forward to partnering with Landos to address the current and future needs of IBD patients."

About Landos Biopharma

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About LianBio

LianBio's mission is to catalyze the development and accelerate the availability of paradigm-shifting medicines to patients in China and major Asian markets through partnerships that provide access to the best science-driven therapeutic discoveries. LianBio collaborates with world-class partners across a diverse array of therapeutic and geographic areas to build out a pipeline based on disease relevance and the ability to impact patients with transformative mechanisms and precision-based therapeutics. For more information, please visit www.lianbio.com.

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oxidative phosphorylation in immune cells, while decreasing differentiation of effector CD4+ T cells, reactive oxygen species, inflammasome formation and production of inflammatory cytokines. The Company reported positive results from the Phase 1a study of NX-13 in healthy volunteers in Q1 2021 and initiated a Phase 1b study of NX-13 in patients with ulcerative colitis in Q2 2021.

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LianBio

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